

## HIGHLIGHTS

- Biotechnology, broadly defined, is the applied use of living organisms or their components to make or modify products, to improve plants or animals and to develop micro-organisms for specific uses. The so-called "new" or second-generation biotechnology refers to the use of recombinant DNA, monoclonal antibody and other modern techniques arising from applications of molecular biology.
- Biotechnology embraces a wide range of industries, from health care to agri-food, environment and the resource sectors, serving as a catalyst to sustainable development. It can lead to new, improved and less expensive products and processes such as the discovery of new drugs and earlier detection and control of diseases; help reduce pollution; and provide crops and food with better yields, value-added traits and processing qualities.
- Considerable controversy exists worldwide concerning the extension of patents to genetic material and life forms and the labelling of food derived from biotechnology.

**There are wide differences in the rate at which biotechnology is being adopted . . .**

- Human health is the most commercially successful application, accounting for over 90 percent of biotechnology products on the market. Biotechnology in agri-food (shortened to ag-bio-tech) is a major source of innovation, but its acceptance in the marketplace is still being debated.
- In mining, forestry, and pulp and paper, applications are still in the formative stage. Product development largely depends on the resources and strategies of individual companies as well as technical and market forces peculiar to each sector.
- Government can create a policy environment that is conducive to the adoption of biotechnology in key sectors of the economy.

**Dedicated biotechnology companies — firms created specifically to exploit the commercial potential of biotechnology — are concentrated in the United States, the United Kingdom, France, Canada and Germany . . .**

- These countries have strong research infrastructure, capital and the industrial capacity to convert basic research into products. The United States, with its particularly strong research base in health care and agriculture, dominates the global market.
- Canada is several years behind the U.S. in commercialization.

**Canada's biotechnology industry has strengths in certain niche areas . . .**

- One area of strength is in vaccines. Canada's medical research infrastructure has initiatives in therapies for cancer, acquired immune deficiency syndrome (AIDS) and neuro-degenerative diseases. The University of Toronto and its affiliated teaching hospitals comprise the largest medical faculty in North America.
- A related Canadian strength is in providing clinical trial services to test the safety and effectiveness of new drugs. These organizations have developed a solid reputation in the U.S. and Europe in large part due to the experience of their medical staffs in conducting clinical trials, their large, multi-ethnic patient base and a public health care system that

provides comprehensive patient information and tracking.

- In the area of crops and animals, Canada has strong research clusters at the universities of Guelph and Saskatoon as well as at the National Research Council's Plant Biotechnology Institute in Saskatoon and at its Institute for Marine Biosciences in Halifax.

- Competitive strengths lie in animal husbandry (embryo transplants and high-quality bovine semen), plant breeding of genetically engineered canola and potatoes, aquaculture vaccines and brood stock optimization, yeast strains and bacterial cultures, and somatic embryogenesis for propagation of conifers and flowers.

## MAJOR TRENDS

**The greatest impact of biotechnology worldwide has been in human health care. This is expected to continue . . .**

- The Canadian biotechnology industry benefits from high consumer demand for innovative, life-saving drugs, high levels of government funding for basic biomedical research, and

the greater availability of investment capital than in other fields because of the prospect of higher returns.

- In other fields, biotechnology is often not a replacement for established tools but an additional approach to solving problems. Consumer acceptance is particularly critical in agri-food if biotechnology is to make significant inroads in the market.

**Throughout the world, government financial and policy support has been critical . . .**

- Such support is needed for basic research, financial assistance to fledgling firms, intellectual property protection, and regulations that expedite commercialization and build consumer confidence in products.

**The international regulatory environment is a major factor in international competitiveness . . .**

- In response to Canadian industry need for an efficient, predictable and flexible regulatory system, products of biotechnology will continue to be administered by existing legislation and regulatory agencies.



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**Sector Competitiveness Frameworks** are a new series of documents produced by Industry Canada in collaboration with Canada's key industry stakeholders. Each framework will examine a major Canadian industry sector, and will be prepared in two volumes. *Part 1 — Overview and Prospects* focusses on the opportunities, both domestic and international, as well as on the challenges facing industry sectors in Canada. *Part 2 — Framework for Action* will be based on discussions with major industrial stakeholders, following study and review of the *Overview and Prospects*.

The objective of the **Sector Competitiveness Frameworks** series is to seek ways in which government and private industry together can strengthen Canada's competitiveness and, in doing so, generate jobs and growth.

In all, some 31 industrial sectors will be analyzed. Electronic copies of documents in the series are available on the Internet at the following address: <http://strategis.ic.gc.ca/scf>

#### **Financing is critical . . .**

- Worldwide, the biotechnology industry, and the health care sector in particular, has experienced losses since inception because of heavy investments in research and development (R&D) and long lead times to commercialization.
- Bringing a new diagnostic product to market takes perhaps three to five years and between \$1 million and \$20 million. For a new crop variety or a new drug, the time is eight to 12 years and the cost is between \$150 million and \$250 million.

**Because biotechnology is research-intensive and employs many people who are highly skilled in a variety of areas, Canada's generous R&D tax credits are extremely important to emerging Canadian companies . . .**

- These incentives also support a strong academic base and enhance employment opportunities for scientists and technicians.

#### **As Canadian firms advance toward commercialization, the human resources needs will shift . . .**

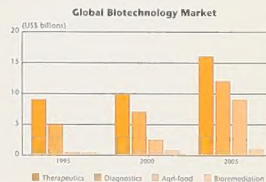
- The changing nature of biotechnology research will require a number of highly specialized scientists with skills in peptide chemistry, gene therapy and bioinformatics, for example.
- Shortages of qualified personnel are starting to appear. Firms are increasingly being forced to look outside the country for people with specific expertise in bioprocessing and preparation of regulatory submissions. The Canadian industry does not yet have the manufacturing expertise to nurture these skills in-house.

**In terms of geographic markets, the United States will remain the first market of choice . . .**

- The U.S. is also the major source of investment. A major challenge for aspiring entrants into the U.S. market is meeting the stringent requirements for health care products set by the U.S. Food and Drug Administration.

#### **The worldwide market for biotechnology-based products is expected to grow from US\$15 billion in 1995 to US\$38 billion in 2005 . . .**

- Bio-pharmaceuticals will continue to hold the dominant share, but growth is expected to slow to 3 percent a year over the rest of the decade, as fewer blockbuster drugs are on the immediate horizon. Immunodiagnostics are the next largest application for biotechnology, with sales projected to increase by 9 percent a year. However, this is a difficult subsector in which to succeed, because international markets are facing pressures to control or lower health care costs and they are already dominated by multinational firms.
- The strongest growth is projected for the agri-food sector, particularly transgenic plants and animal health care.



- In aquaculture, biotechnology opportunities include fish vaccines and pool-side diagnostic tests as well as genetic improvement programs to optimize fish growth rates and feed conversion efficiency.

#### **THE BOTTOM LINE**

**Modern biotechnology has the potential to make a significant contribution to the Canadian economy and to sustainable development through its impact on key sectors such as health care and agri-food . . .**

- Although Canada is not yet a major commercial competitor, it has made important contributions to R&D and has many promising startup and development stage companies with potential in selected niches. There are significant global opportunities but, despite the strong academic research base and magnitude of public and private investment, commercialization has been slow. As in other countries, it has not developed at the pace predicted by early, often optimistic, forecasts.

- The major challenges for governments and industry include:

- addressing consumer concerns with respect to health, safety, information, ethics and the environment, and balancing these against the costs of regulation
- maintaining a strong academic research base and fostering technology transfer mechanisms and industrial capability to convert research into products
- building a domestic manufacturing capability by ensuring competitive costs and returns (i.e. quantifying relative production costs and making the case for investment)
- improving the diffusion of the technology to other sectors of the economy and determining what factors influence its adoption
- improving coordination of training and strategic planning of human resources requirements
- addressing the financing issues — particularly for early-stage, non-health care companies

- attracting investment and alliance partners to support the cost of clinical trials, regulatory approval and international marketing.

For further information concerning the subject matter contained in these Highlights, please contact:

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